UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF DEFENDANT ETHICON, INC.'S MOTION FOR ENTRY OF A PROTECTIVE ORDER PROHIBITING PLAINTIFFS FROM SEEKING ANY FURTHER PRODUCTION OF OUS MATERIALS

In response to Plaintiffs' May 9, 2013 motion to compel (ECF No. 585)—in which Plaintiffs first sought an order compelling Defendant Ethicon, Inc. ("Ethicon") to "produce all foreign regulatory, design, testing, and manufacturing documents"—Ethicon remarked that the motion "reads in part as if it were written for another lawsuit." (Defendant Ethicon, Inc.'s Opposition to Plaintiffs' Motion to Compel, ECF No. 632). The motion to compel, Ethicon pointed out, mentioned neither the parties' extensive negotiations concerning documents housed outside the United States ("OUS" documents) nor Ethicon's prior production of more than a quarter million such documents.

Plaintiffs have now outdone themselves, for their "Memorandum of Law in Support of Plaintiffs' Motion to Compel Production of Defendant's Foreign Documents" (the "Supporting Memorandum") (ECF No. 753) *actually was* written for another lawsuit. From the arguments raised to the cases cited, Plaintiffs' Supporting Memorandum is lifted nearly wholesale from a motion to compel filed in the multidistrict litigation involving American Medical Systems, Inc.

("AMS").[1] Plaintiffs appear to believe that, because the AMS motion to compel concerned OUS documents and because this Court granted that motion to compel, they can obtain a similar result here by framing the issue just the way it was framed in the AMS litigation.

What Plaintiffs fail to grasp, however, is that Ethicon's motion for a protective order raises issues far removed from those presented by the motion to compel in AMS, such that this Court's resolution of the latter has no bearing on the merits of the former. AMS argued that it should not be required to produce *any* OUS documents. Ethicon, on the other hand, contends that it should not be required to produce *any more* OUS documents beyond the nearly 1.6 million pages it has already produced. Not once has Ethicon suggested that its OUS documents are out of bounds due only to the fact that they are located outside of the United States. As a result, Judge Stanley's ruling in AMS Pretrial Order #24 that ordinarily discoverable documents are not protected from discovery simply because they are located outside of the United States does not resolve Ethicon's motion for a protective order, and Plaintiffs' blanket adoption of the briefing giving rise to that ruling is misplaced.

Stripped of the arguments lifted from the AMS litigation, the Supporting Memorandum includes just two novel assertions: that Ethicon's document production in this matter pales in comparison to that of other "global pharmaceutical or medical device companies" in prior multidistrict litigation, and that, in the end, Ethicon's parent company has the financial

[1] Save for three exceptions—the substitution of "Ethicon" for "AMS," the addition of a short introduction, and, ironically, the accusation that Ethicon "makes the same stale arguments made by AMS"—Plaintiffs have copied the "Argument" section of the AMS motion to compel verbatim. *Compare* Supporting Memorandum at 7-14 *with* Memorandum of Law in Support of Plaintiffs' Motion to Compel Production of Defendant's Foreign Documents p. 5-11, ECF No. 280, *In re: American Medical Systems, Inc. Pelvic Repair Systems Products Liability Litigation*, 2:12-md-02325 (S.D. W. Va. Sept. 21, 2012).

wherewithal to absorb the significant burden of requiring Ethicon to produce all OUS documents. To call these assertions red herrings is to give them too much credit. In reality, they are feeble attempts to minimize the substantial amount of OUS documents Plaintiffs have already received, to conceal Plaintiffs' inability to explain why they need yet more of these documents, and to belittle the staggering costs Ethicon would face were it required to produce all that Plaintiffs demand. Plaintiffs' arguments should be rejected and their motion to compel denied.

ARGUMENT

I. The AMS Motion to Compel and Ethicon's Motion for a Protective Order Raise Separate Issues.

By their motion to compel, the plaintiffs in the AMS MDL (the "AMS plaintiffs") presented a "narrow issue" for Judge Stanley's resolution: "whether AMS's duty to produce responsive documents may be confined to only those documents that happen to be located within the United States." Memorandum of Law in Support of Plaintiffs' Motion to Compel Production of Defendant's Foreign Documents, p. 1, ECF No. 280, *In re: American Medical Systems, Inc. Pelvic Repair Systems Products Liability Litigation*, 2:12-md-02325 (S.D. W. Va. Sept. 21, 2012). The AMS plaintiffs argued that the duty to produce did not stop at the United States borders, and they cited a host of cases allegedly supporting the proposition that ordinarily discoverable material may not be withheld solely on the basis that such material is housed outside the United States. *Id.* at 6.

In response, AMS drew a line in the sand: It "agreed to produce foreign non-privileged documents located in the United States that [were] otherwise responsive," but it refused to produce foreign documents "located in countries outside the United States." Memorandum of

Law in Opposition to Plaintiffs' Motion to Compel Production of Defendant's Foreign Documents, p. 12, ECF No. 304, *In re: American Medical Systems, Inc. Pelvic Repair Systems Products Liability Litigation*, 2:12-md-02325 (S.D. W. Va. Oct. 5, 2012). AMS went so far as to argue that it had no obligation even to search for, gather, or review OUS documents. *Id.* at 8.

By Pretrial Order #24, Judge Stanley rejected AMS's position, noting that "it is well-settled that foreign companies related to American domestic companies are subject to production of their relevant documents." Pretrial Order #24, p. 1, ECF No. X, *In re: American Medical Systems, Inc. Pelvic Repair Systems Products Liability Litigation*, 2:12-md-02325 (S.D. W. Va. Oct. 30, 2012) (hereinafter "Pretrial Order #24"). Judge Stanley found that the AMS plaintiffs' requests for OUS materials were reasonable because foreign adverse reports "are as relevant as those from the United States"; because "[m]edical research on the efficacy of such products is relevant whether it is written in Greek or English"; and because "AMS's pelvic repair products were manufactured in the United States and Ireland, but they have been, and are, implanted in women worldwide." *Id.* at 4. As such, Judge Stanley directed that AMS produce its relevant and responsive OUS documents, but warned AMS "not to burden the depository with materials which are duplicates of documents kept in the United States and already produced to the depository." *Id.*

Plaintiffs' Supporting Memorandum in this case leaves one with the impression that Ethicon has taken a similar stance with respect to its OUS documents, which is not surprising given that the Supporting Memorandum was essentially drafted by the AMS plaintiffs in response to AMS's refusal to produce any foreign documents. Yet Plaintiffs ignore several critical differences. Whereas AMS argued it had no duty to search for or gather OUS documents, Ethicon has voluntarily searched the files of approximately fifty-two foreign

custodians, along with other OUS central sources and databases. *See* Declaration of Pamela Downs ¶ 13, ECF No. 632-4 (hereinafter "Downs Declaration"). Whereas AMS produced only those adverse event reports found in the United States, Ethicon has voluntarily produced world-wide adverse event reports for the products at issue in this litigation. *Id.* Whereas AMS refused to produce any foreign regulatory documents, Ethicon has voluntarily collected, translated, and produced regulatory documents from Japan, France, and Australia, all countries of Plaintiffs' choosing. Whereas AMS maintained that its foreign marketing materials were off the table, Ethicon has searched for and produced the unique marketing materials for thirty-two separate countries. Whereas AMS produced design, testing, and manufacturing documents only if they were located in the United States, Ethicon has worked to produce relevant design and testing documents, irrespective of country-of-origin, and relevant manufacturing documents for lots identified with a particular plaintiff's claims, including documents located outside the United States. Put simply, whereas AMS refused to produce a single document housed in a foreign country, Ethicon has voluntarily produced 250,000 OUS documents, amounting to nearly 1.6 million pages of material. In light of these differences, Pretrial Order #24 from the AMS MDL is not the be-all and end-all Plaintiffs claim it to be.

Plaintiffs also fail to acknowledge that Ethicon has produced those OUS documents that Judge Stanley specified were particularly relevant. Judge Stanley made clear, for example, that foreign adverse event reports are as relevant as those generated in the United States. As mentioned, Ethicon has produced world-wide adverse event reports. Judge Stanley noted that medical research regarding product efficacy is relevant, regardless of the country in which the research was performed. Ethicon has produced its relevant testing documents, irrespective of whether those documents are stored in the United States.

In fact, by its motion for a protective order, Ethicon is simply seeking to prevent production of those documents Judge Stanley ruled need not be produced. In Pretrial Order #24, Judge Stanley directed AMS "not to burden the depository with materials which are duplicates of documents" already produced. Pretrial Order #24 at 4. If Ethicon is required to produce yet more OUS documents, those additional documents will likely be largely duplicative of the materials Ethicon has already produced. For example, Ethicon has already produced regulatory submissions made in Japan, France, and Australia. Regulatory submissions from other countries will largely duplicate what Plaintiffs already have, for regulatory submissions do not vary significantly from one country to another. *See* Downs Declaration ¶¶ 5-11. Just as the AMS plaintiffs should not have been "burden[ed]" with such duplicative material, Ethicon should not be put to the burden of having to produce it. *See* Pretrial Order #24 at 4.

In sum, because Ethicon has produced vast amounts of OUS documents, the AMS briefing and resulting Pretrial Order #24—which addressed only whether OUS documents were discoverable to begin with—do not resolve the issue presented by Ethicon's current motion for a protective order. What this Court must now resolve is a separate issue, namely, whether Ethicon should be forced to produce yet more OUS documents that are largely duplicative of those already produced. As explained in Ethicon's motion and incorporated memorandum, such a production would yield little to no benefit to Plaintiffs, yet would impose a significant burden on Ethicon. *See* Downs Declaration ¶¶ 10-11, 17 (explaining that to collect additional OUS documents would require identifying point of contact in at least sixty-seven countries and locating and translating documents in each country). Accordingly, Ethicon's motion should be granted, and Plaintiffs should be precluded from seeking any further discovery of Ethicon's OUS documents. Alternatively, in light of the unlikelihood that additional discovery of OUS

documents will reveal any information of benefit, Plaintiffs should be ordered to bear the significant cost of that discovery, including translation of and privilege review of the documents produced.

II. Plaintiffs Have Misrepresented Ethicon's Position.

As explained in the motion for a protective order, Ethicon's attempt to secure a geographic limitation on the extent of discovery allowed is primarily limited to regulatory OUS documents. *See* Motion for Protective Order at 4 n.4. With respect to design, testing, and manufacturing documents, Ethicon has endeavored to—and will continue to—produce relevant OUS documents, regardless of whether the documents are located in the United States or abroad. But regulatory submissions are largely duplicative from one country to the next, meaning that Plaintiffs are likely to derive little to no benefit from the production of additional regulatory OUS documents. This trivial benefit is even more apparent when one considers that courts are nearly unanimous in holding that such documents are inadmissible. *See id.* at 6-8. As a result, Ethicon's motion for a protective order is aimed primarily at regulatory submissions.

Perhaps because it was crafted in response to a different discovery dispute involving a different manufacturer in a different case, the Supporting Memorandum ignores the narrow focus of Ethicon's motion for a protective order, instead claiming that Ethicon seeks to impose "an arbitrary limit" and withhold production of OUS documents "simply because the discovery sought is outside of the United States." Supporting Memorandum at 3. Plaintiffs go on to cite examples of documents they maintain have been unreasonably withheld. *Id.* at 5, 11. All of their examples, however, concern safety and efficacy issues, not regulatory OUS submissions.

Again, Ethicon does not object to producing OUS mesh documents pertaining to health and safety. Ethicon has conducted searches for such documents, is investigating the issues

Plaintiffs raise to make sure that such documents, if any, were produced, and will make reasonable efforts to obtain them if they have not been. Ethicon does object, however, to an unlimited fishing expedition of irrelevant regulatory documents, which would impose a substantial burden on Ethicon yet provide little to no benefit to Plaintiffs. Nowhere in the Supporting Memorandum do Plaintiffs offer a valid explanation as to why production of more regulatory documents is necessary in this case.

III. The Vioxx MDL is Inapposite Here.

Ignoring Ethicon's expansive production of OUS documents is not the only strategy Plaintiffs employ in their Supporting Memorandum. They also attempt to minimize that production by comparing it to the document productions made in other multidistrict litigations. "[I]t is not uncommon for global pharmaceutical or medical device companies to produce many millions of documents," Plaintiffs say, pointing to the Vioxx MDL as an example. Supporting Memorandum at 1. Plaintiffs claim that, as part of that MDL, Merck produced more than fifty million documents and participated in more than two thousand depositions.[2] *Id.* The implication, of course, is that Ethicon should not be celebrated for producing nearly ten million documents in this litigation.

To begin, Plaintiffs' suggestion that one can assess the adequacy of a litigant's document production by comparing it to other cases involving other products and other litigants is nonsense. Rule 26 of the Federal Rules of Civil Procedure mandates a limitation on the extent of discovery upon a showing of, among other things, undue burden or unreasonable duplication.

[2] Ethicon has a reasonable and good faith belief that Merck actually produced fifty million *pages* of documents rather than fifty million *documents*. *See, e.g.*, *In re: Vioxx® Litigation*, Case No. 619, p. 5 (Sup. Ct. N.J. Nov. 9, 2007) (attached hereto as Exhibit 1) (noting that "[m]ore than 54 million *pages of documents* . . . have been produced by Merck" (emphasis added)).

See Fed. R. Civ. P. 26(b)(2)(C). Not surprisingly, Rule 26 does not include as a factor for consideration how the litigant's production compares to document productions in unrelated litigation. *See id.*

In any event, comparing the size of Ethicon's production of OUS documents relating to pelvic mesh against the production by one of the world's largest pharmaceutical companies in litigation involving one of the most prescribed pharmaceutical drugs is hardly an appropriate comparison. "It is estimated that 105 million prescriptions for Vioxx were written in the United States" in the five years that it was on the market and "that approximately 20 million patients have taken Vioxx in the United States" alone. *In re Vioxx Products Liability Litigation*, 760 F. Supp. 2d 640, 642 (E.D. La. 2010). When problems with Vioxx allegedly surfaced, a multidistrict litigation formed that, at its peak, included nearly fifty thousand claimants. *Id.* at 646. Given these numbers, it is not at all surprising that Merck produced the amount of documents it did in the Vioxx litigation.

This MDL involves but a fraction of the claimants as did the Vioxx MDL. As of September 3, 2013, there are 9,535 cases pending in this MDL, or less than twenty percent of the Vioxx claims. More importantly, the size of the business of Ethicon Women's Health and Urology, when measured by sales or by number of employees, pales in comparison to Merck's size and Vioxx business. Merck employed a 3,000-person sales force for Vioxx (compared to approximately one hundred current sales representatives for EWHU), and the Vioxx new drug application totaled 278 volumes.[3] Of course Merck produced more documents in the Vioxx

[3] *See* David R. Culp, *Merck and the Vioxx Debacle: Deadly Loyalty*, 22 St. John's J. Legal Comment. 1, 29 n.169 (2007) (Vioxx sales force); Merck Research Laboratories, Original New Drug Application, NDA 21-042 (Nov. 23, 1998), *available at* dida.library.ucsf.edu/pdf/oxx15t10 (size of Vioxx NDA).

MDL. That fact has absolutely no bearing on Ethicon's motion for a protective order, the merits of which must be assessed based on the burden imposed on Ethicon in this litigation.

IV. Johnson & Johnson's Resources are Irrelevant.

Equally irrelevant are Johnson & Johnson's annual earnings, which Plaintiffs claim to include to "put . . . in to perspective" Ethicon's argument that production of all OUS documents would constitute an undue burden. *See* Supporting Memorandum at 2, 14. Plaintiffs insinuate, of course, that whatever burden would result to Ethicon from production of the remaining OUS documents, that burden would be minimal in relation to the resources of "one of the world's largest pharmaceutical and medical device manufacturers." *Id.* at 2.

Although the "parties' resources" is one of several factors to be considered when a litigant seeks an order limiting the extent of discovery, *see* Fed. R. Civ. P. 26(b)(C)(iii), Plaintiffs have offered no support for their theory that it is the resources of the litigant's parent company that are relevant. That would be an odd outcome, given that Johnson & Johnson is a holding company that, contrary to Plaintiffs' assertions, does not manufacture medical devices. Ethicon is but one of its more than 275 operating companies around the world. Its ability or inability to shoulder the significant burden of producing OUS documents in this matter is simply irrelevant, for that burden falls squarely on Ethicon. And as explained in the motion for a protective order and incorporated memorandum, that burden far outweighs what little benefit Plaintiffs would derive from yet more OUS documents.

CONCLUSION

For the reasons set forth above, Ethicon respectfully requests that this Court grant Ethicon's motion for a protective order and deny Plaintiffs' motion to compel production of

foreign documents or, in the alternative, order Plaintiffs to pay the costs associated with the collection, review, and production of additional OUS documents produced.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on September 5, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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